(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
7 November 2002 (07.11.2002)

PCT

(10) International Publication Number
WO 02/087468 A1

(51) International Patent Classification[7]: A61F 2/00

(21) International Application Number: PCT/EP02/03459

(22) International Filing Date: 27 March 2002 (27.03.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
101 21 193.7 30 April 2001 (30.04.2001) DE

(71) Applicant *(for all designated States except US)*: **ETHICON GMBH** [DE/DE]; Robert-Koch-Strasse 1, 22851 Norderstedt (DE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **WALTHER, Christoph** [DE/DE]; Dorfstrasse 35, 24568 Kattendorf (DE). **SCHULDT-HEMPE, Barbara** [DE/DE]; Rosenstrasse 23, 24576 Bad Bramstedt (DE). **HOREYSECK, Guenter** [DE/DE]; Thüringer Allee 11, 53757 Sankt Augustin (DE).

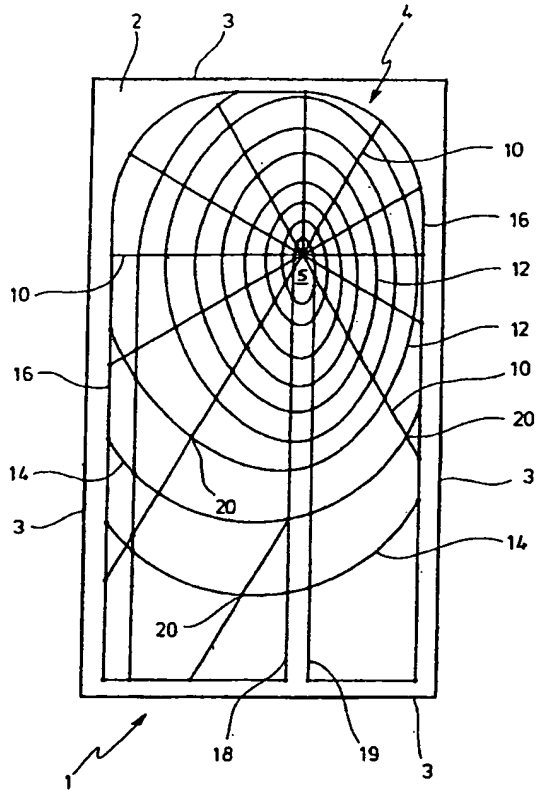
(74) Agents: **BOTH, Georg** et al.; Uexküll & Stolberg, Beselerstrasse 4, 22607 Hamburg (DE).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

(54) Title: AREAL IMPLANT



(57) Abstract: An areal implant (1) has a flexible, porous basic structure (2) made from resorbable material and a flexible, spider's web-like reinforcing structure (4) made from non-resorbable material. The reinforcing structure (4) contains generally radially-running radial elements (10, 18, 19) and connection elements (12, 14, 16) running transversely to the radial elements (10, 18, 19).

WO 02/087468 A1

Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Areal Implant

The invention relates to an areal implant, which can be used in particular for the treatment of inguinal hernias.

There is a world-wide trend in the surgical treatment of an inguinal hernia towards as stress-free as possible a repair with the help of prosthetic mesh material. A preferred surgical technique is the Lichtenstein technique, in which the spermatic cord is pushed through a slit in the implant mesh used, so that it comes to rest in the middle area of the mesh.

A preferred material for implant meshes is polypropylene, as it has a relatively high strength in the body of a patient and displays long-term stability and is largely chemically inert. Implant meshes made from polypropylene also have disadvantages, however. A chronic reaction to foreign bodies is induced, i.e. a chronic wound forms in the area of the implant. The effects on the immune system are still not known. Furthermore, a ca. 20% deformation of the implant mesh can lead to hard scar plates, so that an explantation of the mesh can become necessary. The long-term effect of such an implant on the organism is unknown, as there are no studies extending over 30 to 50 years.

Commercial monofilament implant meshes for the treatment of inguinal hernias typically have an area weight of 90 to 100 g/m^2. A sufficient strength is then guaranteed at all times after the operation.

EP 1 025 821 A1 shows a product, which can also be used as implant mesh for the treatment of hernias, which consists of three layers. A separately embroidered layer serving as a spacer is connected on both sides to another layer. The surface has a plurality of openings which are arranged in at least two hole patterns with significantly different hole sizes.

An implant developed especially for the Lichtenstein technique is known from WO 00/67663. A commercial implant mesh for hernia surgery is provided in a section with an anti-adhesive layer in order to avoid deformities on the spermatic cord.

A further implant mesh for the treatment of hernias is shown in WO 99/51163. This mesh has two resorbable layers, the one layer being able to be quickly resorbed and the other layer being able to be slowly resorbed.

A textile surgical implant with a resorbable backing material is described in US 5 990 378 onto which a mesh structure is embroidered in a regular pattern. The backing material helps with the positioning of the implant during the surgery.

It is the object of the invention to provide an areal implant which can be used, e.g., for repairing an inguinal hernia and guarantees the surgery's success while avoiding the above-mentioned long-term problems.

This object is achieved by an areal implant with the features of claim 1. Claim 12 relates to a process for preparing such an implant. Advantageous designs of the invention emerge from the dependent claims.

The areal implant according to the invention has a flexible, porous basic structure made from resorbable material and a flexible, spider's web-like reinforcing structure made from non-resorbable material. The reinforcing structure has generally ra-

dially-running radial elements and connection elements running transverse to the radial elements. At least part of the connection elements can be continuous and run as a whole in the form of a spiral. It is also conceivable that at least part of the connection elements forms curves which are closed in themselves and run alongside each other.

Thus, the reinforcing structure looks similar to a spider's web. The radial elements need not all converge on one point, but they are more dense in the central area of the implant (which does not have to lie in the geometric centre). Similarly, the connection elements can have a greater density in the central area, as is the case for many types of spirals. The result is that the reinforcing structure is strong enough in the central area of the implant, i.e. where a particularly high stress occurs in a patient after implantation. A sufficient strength is guaranteed in the outer areas of the implant even with a material density that is generally lower (as is typical of a spider's web structure).

The spider's web-like reinforcing structure matched to the stresses which occur in the patient permits a dramatic reduction in the amount of non-resorbable material in the implant. While, e.g., commercial monofilament implant meshes for the treatment of inguinal hernias with a unit weight of 90 to 100 g/m^2 and a size of 15 cm x 7 cm (as is normal for the Lichtenstein technique) require a thread length of 50 to 60 m per implant, the reinforcing structure of the implant according to the invention manages with a thread length of, e.g., 9 m.

The flexible, porous basic structure consists of resorbable material. The handling of the implant during the surgery is much improved by the basic structure. Furthermore, during the early phase of the healing process, connective tissue grows into the basic structure, which is still not resorbed, which leads to an

early increase in strength and is necessary for the healing process as a whole.

In an advantageous embodiment of the invention, connection elements and radial elements of the spider's web-like reinforcing structure are attached to each other at intersections, and preferably knotted. Two radial elements running alongside each other can be provided (which are preferably aligned parallel to each other) between which the implant for forming a slit can be incised when using the surgery technique according to Lichtenstein. The implant can preferably be trimmed by cutting between connection elements running alongside each other.

Such designs enable the implant to be adapted to the anatomical circumstances of the patient before or during the surgery (fashioning). As connection elements and radial elements of the spider's web-like reinforcing structure are attached to each other at intersections, there is no need to fear that the cuts required for trimming to the desired shape or for forming a slit for the spermatic cord according to the Lichtenstein technique damage the reinforcing structure so that it can no longer fulfil its function. When trimming, for example the outer "rings" or "spiral coils" of the spider's web-like reinforcing structure can be cut off. If the reinforcing structure has a different colour from the basic structure, the necessary cuts between the elements of the reinforcing structure are made easier.

The basic structure is preferably warp-knitted but can also be prepared as another textile structure.

In an advantageous design of the invention, the reinforcing structure, which preferably contains monofilaments and/or multifilaments, is embroidered onto the basic structure. Through embroidering, a spider's web-like reinforcing structure in any form can be produced in a simple way, it also being possible to form knot structures at the intersections between connection

elements and radial elements. The basic structure serves as backing during the embroidering process. After the basic structure is resorbed in the patient's body after the implantation, the reinforcing structure is self-supporting and manages without the basic structure.

Preferred resorbable materials for the basic structure are copolymers of L-lactide and glycolide, e.g. in the mass ratio 10:90 (e.g. Vicryl®, Ethicon) or in the mass ratio 95:5 (e.g. Panacryl®, Ethicon), poly-p-dioxanone (PDS), copolymers of glycolide and ε-caprolactone, e.g. in the mass ratio 75:25 (e.g. Monocryl®, Ethicon) or mixtures of such materials, but other resorbable materials are also conceivable.

The reinforcing structure comprises non-resorbable material, a term which is also taken to include very slowly resorbable materials (e.g. polyesters). Polypropylene (e.g. Prolene®, Ethicon), polyamide (e.g. Ethilon®, Ethicon, from polyamide 6), polyester, polyethylene terephthalate (PET) (e.g. Mersilene®, Ethibond®, Ethicon) as well as mixtures of polyvinylidene fluoride (PVDF) and copolymers of vinylidene fluoride and hexafluoropropene (e.g. Pronova®, Ethicon) are particularly suitable. Mixtures, also e.g. in the form of multifilaments, of these materials or other non-, or very slowly, resorbable materials are also possible.

The implant according to the invention is thus characterized by a high long-term compatibility in the body of a patient, as the non-resorbable proportion of foreign bodies is dramatically reduced compared with conventional implant meshes. No small-pored mesh with an uncertain long-term effect remains, but simply a spider's web-like reinforcing structure of low mass, which is matched to the anatomical circumstances and the occurring forces. This is comparable with the "biological" surgery according to Shouldice.

The resorbable basic structure helps with the positioning of the implant and is a temporary support in the first weeks after the surgery. During this time, a fibrohystiocytic reaction is induced, connective tissue growing into the implant (early phase of the healing process). During the following intermediary phase there is a resorption of the basic structure with substitution by connective tissue. After the healing-in process has finished, only the spider's web-like reinforcing structure remains in the body of the patient and fulfils a holding function (late phase), as already discussed.

The invention is explained in more detail in the following, using embodiments. The drawing shows in

Figure 1 a top view of a version of the implant according to the invention.

A version of a flexible, areal implant 1 is represented in Figure 1 in top view. The implant 1 has a basic structure 2 which is flexible and porous and is made from resorbable material. In the embodiment, the basic structure 2, whose edge is numbered by 3, is warp-knitted in the conventional way, with a closed, small-pored warp-knit structure. The size of the implant 1 or of the basic structure 2 is approx. 7.5 cm x 15 cm in the embodiment.

Examples of materials of the basic structure 2 are PDS, Vicryl®, Monocryl® and Panacryl®, as explained in more detail above; for simplicity's sake, the abbreviations are used here. The thread material used for the basic structure can contain monofilaments or multifilaments, mixtures also being conceivable.

A flexible, spider's web-like reinforcing structure 4 is placed onto the basic structure 2. In the embodiment, the reinforcing structure 4 is embroidered onto the basic structure. During the embroidering process, the basic structure 2 has the function of

a backing mesh. The reinforcing structure 4 consists of a non-resorbable material and becomes self-supporting when the basic structure 2 is resorbed after the implant 1 has been implanted.

Polypropylene, Pronova®, polyethylene terephthalate and/or polyamide 6, e.g., are considered as material for the reinforcing structure 4, as already explained above. The reinforcing structure preferably consists of monofilaments and/or multifilaments of the referenced materials, mixed forms also being possible, e.g. the use of multifilament yarns with filaments from different materials. Typical thread thicknesses of the monofilaments or multifilaments are 3 mil to 6 mil (1 mil = 0.0254 mm), this selection being non-restrictive.

The reinforcing structure 4 is similar to a spider-web. However, no circular structure is realised in the embodiment, as in the most common spider's wheel network, but more of an elliptical structure. The centre of the reinforcing structure is at 5, i.e. not in the geometric centre of the implant 1. The elliptical design of the reinforcing structure 4 is advantageous, as the area to be covered with the implant 1 in the groin of a patient with medial and lateral hernia gaps resembles the shape of an ellipse. The reinforcing structure 4 has a structuring with a concentrated quantity of thread in the area in which possible relapses are to be expected, i.e. between internal inguinal ring and mons pubis, i.e. in the area of the medial and lateral hernia gaps.

In detail, the reinforcing structure 4 contains radial elements 10, which generally run radially and more or less (but not necessarily exactly) start from the centre 5.

Connection elements 12 extend transversely to the radial elements 10. In the embodiment, the connection elements cohere in the area of the centre 5 and run as a whole in the form of a spiral. Further out are connection elements 14 which do not co-

here with the spiral of the connection elements 12. Furthermore, a largely closed connection element 16 runs alongside the edge 3 of the basic structure 2.

Two radial elements 18 and 19 extend parallel to each other roughly from the centre 5 to the edge 3 of the basic structure 2. The implant 1 can be incised between the radial elements 18 and 19 in order to form a slit matched to the patient, to accommodate the spermatic cord.

When embroidering the reinforcing structure 4 onto the basic structure 2, the thread material is interwoven in the manner of knots at the intersections numbered 20 between the radial elements 10, 18, 19 and the connection elements 12, 14, 16, so that the reinforcing structure 4 is self-supporting and stable even after the resorption of the basic structure 2.

The knot-like intersections 20 ensure in particular that the reinforcing structure 4 also at least largely retains its stability when a cut is made laterally into the implant 1 in the course of the surgery. Thus, through a cut between the radial elements 18 and 19, a slit can be formed with the surgery technique according to Lichtenstein, as already mentioned. Furthermore, it is possible to trim the implant 1 medially and cranially along the edge 3 according to the individual situation of the patient. The cuts necessary for this preferably run between and largely parallel to the connection elements 12, 14, 16. The intersections 20 should not be damaged when cutting.

In order to facilitate the cutting and trimming of the implant 1 and to prevent an unintentional cutting into the reinforcing structure 4, the reinforcing structure 4 is preferably distinguished from the basic structure 2 by its colour. A coloured reinforcing structure 4 also allows better recognition of the edge area of the reinforcing structure 4 which should also be included when fixing the implant 1 in the course of the surgery so

that the reinforcing structure 4 can reliably fulfil its function.

Suitable as dyes are, e.g., copper phthalocyanine blue (C.I.: 74160; in particular for colouring polypropylene and Pronova®), D & C Green No. 6 (C.I.: 61565; in particular for colouring polyethylene terephthalate) as well as Pigment Blue 9860/Chromophtal Blue A3R (C.I. Pigment Blue 60; in particular for colouring polyamide 6).

In Table 1, the material of the basic structure 2, the material of the reinforcing structure 4 and the stitch type for the reinforcing structure 4 are given for six embodiments. In these examples, the reinforcing structure 4 was embroidered onto the basic structure 2 using a I0211-495 MSCI type embroidery machine manufactured by ZSK-Stickmaschinen GmbH.

In Table 2, the material consumption of commercial non-resorbable implants is compared with that of two versions of the implant according to the invention. The commercial implants are designated with their trade names Marlex® Mesh (made from polypropylene; manufacturer: Bard), Atrium® Mesh (made from polypropylene; manufacturer: Atrium Medical Corporation) and Prolene® Mesh (made from polypropylene; manufacturer: Ethicon GmbH) and consist essentially of a largely homogeneous mesh structure without additional reinforcing structure. The implant weight is relative to a size of 7,5 cm x 15 cm and in the two versions of the implant according to the invention to the state after resorption of the basic structure. 1 mil = 0.0254 mm. It is seen that the reinforcing structure remaining permanently in the patient of the implant according to the invention is much lighter than the commercial implants.

Table 1

No.	Material of the basic structure	Material of the reinforcing structure	Stitch type
1	Fine-pored mesh made from Vicryl®	Upper thread: 3.5 mil Pronova® Bottom thread: 5 mil Pronova®	Flat stitch: 0.4 mm 2 backing lines 1.5 mm
2	Medium-pored mesh made from Panacryl®	Upper thread: 3.5 mil Prolene® Bottom thread: 3.5 mil Prolene®	Flat stitch: 0.4 mm 2 backing lines 1.5 mm
3	Fine-pored mesh made from PDS	Upper thread: 5 mil Ethilon® Bottom thread: 3.5 mil Ethilon®	Locking lines 2.4 mm 2 backing lines: 1st line straight, 2nd line lapped stitch length 1.5 mm lap 0.2 mm
4	Medium-pored mesh made from Monocryl®	Upper thread: 5 mil Pronova® Bottom thread: 3.5 mil Pronova®	Locking lines 2.4 mm 2 backing lines: 1st line straight, 2nd line lapped stitch length 1.5 mm lap 0.2 mm
5	Medium-pored mesh made from Panacryl®	Upper thread: 5 mil Pronova® Bottom thread: 3.5 mil Pronova®	Locking lines 2.3 mm 2 lines: both straight stitch length 1.5 mm cross-boll connection
6	Medium-pored mesh made from Monocryl®	Upper thread: 5 mil Pronova® Bottom thread: 3.5 mil Pronova®	Locking lines 2.2 mm 2 lines: 1st line straight, 2nd line lapped stitch length 1.5 mm cross-boll connection

Table 2

	Marlex®	Atrium®	Prolene®	Implant 2 according to the invention	Implant 1 according to the invention
Implant weight (g)	0.99	0.96	1.05	0.09	0.15
Thread thickness (mil)	6	5	6	3.5	5
Necessary thread length (m)	56	57	60	12	9

Claims

1. Areal implant, with
- a flexible, porous basic structure (2) made from resorbable material and
- a flexible, spider's web-like reinforcing structure (4) made from non-resorbable material with generally radially-running radial elements (10, 18, 19) and connection elements (12, 14, 16) running transversely to the radial elements (10, 18, 19).

2. Implant according to claim 1, characterized in that at least part of the connection elements (12) is continuous and runs as a whole in the form of a spiral.

3. Implant according to claim 1 or 2, characterized in that at least part of the connection elements forms curves which are closed in themselves and run alongside each other.

4. Implant according to one of claims 1 to 3, characterized in that connection elements (12, 14, 16) and radial elements (10, 18, 19) are attached to each other at intersections (20), preferably knotted.

5. Implant according to one of claims 1 to 4, characterized by two radial elements (18, 19) running alongside each other, between which the implant (1) can be incised for forming a slit when using the surgical technique according to Lichtenstein.

6. Implant according to one of claims 1 to 5, characterized in that the implant (1) can be trimmed by cutting between connection elements (12, 14, 16) which run alongside each other.

7. Implant according to one of claims 1 to 6, characterized in that the basic structure (2) is warp-knitted.

8. Implant according to one of claims 1 to 7, characterized in that the reinforcing structure (4) comprises monofilaments and/or multifilaments.

9. Implant according to one of claims 1 to 8, characterized in that the reinforcing structure (4) is embroidered onto the basic structure (2).

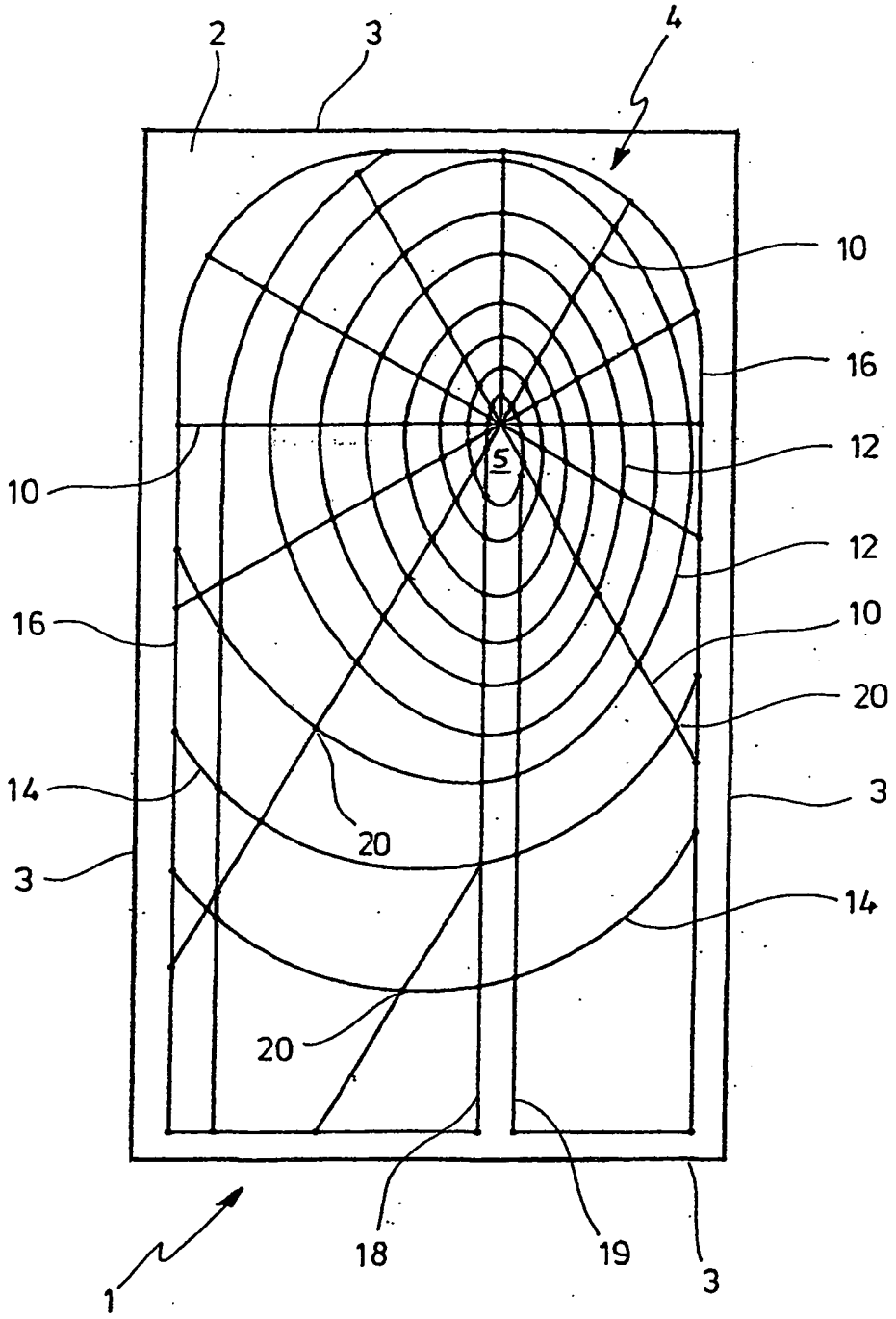
10. Implant according to one of claims 1 to 9, characterized in that the reinforcing structure (4) has different colour from the basic structure (2).

11. Implant according to one of claims 1 to 10, characterized in that the basic structure (2) contains at least one material from the following group: L-lactide/glycolide copolymers, poly-p-dioxanone, glycolide/ε-caprolactone copolymers.

12. Implant according to one of claims 1 to 11, characterized in that the reinforcing structure (4) contains at least one material from the following group: polypropylene, polyamide, polyester, polyethylene terephthalate, mixtures of polyvinylidene fluoride and copolymers of vinylidene fluoride and hexafluoropropene.

13. Process for the manufacture of an areal implant, in which a flexible, spider's web-like reinforcing structure (4) made from non-resorbable material with generally radially-running radial elements (10, 18, 19) and connection elements (12, 14, 16) running transversely to the radial elements (10, 18, 19) is embroidered onto a flexible, porous basic structure (2) made from resorbable material.

FIG.1



INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/03459

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 2 604 085 A (AUDION MICHEL) 25 March 1988 (1988-03-25) page 3, line 20 - line 27; claims 1,2; figure 4	1,3,6,8, 9,13
A	page 5, line 3 - line 9	4
Y	US 5 990 378 A (ELLIS JULIAN GARTH) 23 November 1999 (1999-11-23) cited in the application column 2, line 18 - line 21; figure 1	1,3,6,8, 9,13
A	WO 01 15625 A (SCHULDT HEMPE BARBARA ;WALTHER CHRISTOPH (DE); ETHICON GMBH (DE)) 8 March 2001 (2001-03-08) page 5, paragraph 2 -page 7, paragraph 2; figures	1,7,8, 10-12

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 August 2002	26/08/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/03459

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 93 17635 A (BARD INC C R) 16 September 1993 (1993-09-16) claims 1,3,8,13-15; figures	1,8
A	US 5 954 767 A (PAJOTIN DOCTEUR PHILIPPE ET AL) 21 September 1999 (1999-09-21) column 2, line 20 - line 27; figures	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 02/03459

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2604085 A	25-03-1988	FR 2604085 A1	25-03-1988
		WO 8801853 A1	24-03-1988
US 5990378 A	23-11-1999	EP 0744162 A2	27-11-1996
WO 0115625 A	08-03-2001	DE 19942611 C1	05-07-2001
		WO 0115625 A1	08-03-2001
		EP 1210031 A1	05-06-2002
WO 9317635 A	16-09-1993	AU 3784793 A	05-10-1993
		WO 9317635 A1	16-09-1993
		US 5593441 A	14-01-1997
US 5954767 A	21-09-1999	FR 2709947 A1	24-03-1995
		EP 0746267 A1	11-12-1996
		WO 9507666 A1	23-03-1995
		US 6368541 B1	09-04-2002